EPA REQUIREMENTS FOR QUALITY MANAGEMENT PLANS

EPA QA/R-2

United States Environmental Protection Agency
Quality Assurance Management Staff

Washington, DC 20460

D R A F T I N T E R I M F I N A L

AUGUST 1994

U.S. Environmental Protection Agency Quality System Series

This document is one of the *U.S. Environmental Protection Agency Quality System Series* requirements and guidance documents. These documents describe the EPA policies and procedures for planning, implementing, and assessing the effectiveness of the Quality System. Requirements documents (identified as EPA QA/R-x) establish criteria and mandatory specifications for quality assurance (QA) and quality control (QC) activities. Guidance documents (identified as EPA QA/G-x) provide suggestions and recommendations of a non-mandatory nature for using the various components of the Quality System.

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FOREWORD

The U.S. Environmental Protection Agency (EPA) has developed the Quality Management Plan (QMP) as a means of documenting how an organization will plan, implement, and assess the effectiveness of quality assurance (QA) and quality control (QC) operations applied to environmental programs. The process of planning, implementing, and assessing these management systems is called *quality management* and the product of this process is called the *Quality System*.

EPA has developed a mandatory Agency-wide Quality System (or QA program) that requires all organizations performing work for EPA to assure that:

- environmental data collected are of the appropriate type and quality for their intended use, and
- environmental technology used for pollution control or waste remediation are designed, constructed, and operated according to defined specifications and protocols.

The development, review, approval, and implementation of the QMP is part of the mandatory Agency-wide Quality System that requires all organizations performing work for EPA to develop and operate management processes and structures for assuring that data or information collected are of the needed and expected quality for their desired use. The QMP is an integral part of the fundamental principles of Quality Management which form the foundation of the Agency's Quality System.

This document contains essentially the same requirements as Chapter 4 of the *U.S. EPA Quality Manual for Environmental Programs*, for EPA organizations. This document provides the QAPP requirements in an external publication primarily for non-EPA organizations that conduct environmental data operations in behalf of EPA through contracts, financial assistance agreements, and interagency agreements; however, it may be used by EPA as well. Another reference which may be helpful to the user is:

EPA QA/R-1 EPA Quality Systems Requirements for Environmental Programs

A companion document to this one provides suggestions on preparing, reviewing, and implementing QMPs. This document is:

EPA QA/G-2 Guidance for Developing, Reviewing, and Implementing Quality Management Plans

ACKNOWLEDGEMENTS

This document reflects the collaborative efforts of many quality management professionals throughout the Environmental Protection Agency, who are participating in the challenge for continuous improvement in quality systems supporting environmental programs. These individuals, representing the EPA Regional Offices, Program Office organizations, and research and development laboratories, provide a diverse and broad range of needs and experiences in environmental data collection programs. Their contributions and the comprehensive reviews provided by members of the EPA quality community during the development of this document are greatly appreciated.

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CHAPTER I

INTRODUCTION

Environmental programs conducted in behalf of the U.S. Environmental Protection Agency (EPA) involve many diverse activities that address complex environmental issues. The EPA annually spends several hundred million dollars in the collection of environmental data[1] for scientific research and regulatory decision-making. In addition, the regulated community may spend as much as an order of magnitude more each year to respond to Agency compliance requirements. Furthermore, EPA is increasingly involved in the use of environmental technology for pollution control and waste clean-up, often specifying the use of particular technologies in permits and regulations.

Environmental data are critical inputs to decisions involving the protection of the public and the environment from the adverse effects of pollutants from natural and man-made sources. Such sources may include waste operations and industrial discharges. Similarly, environmental data are key inputs to decisions and actions pertaining to environmental protection efforts in air, land, forests, fresh water, oceans, estuaries, and ground water.

The success of environmental technology in abating pollutant emissions and effluent discharges, or in remediating waste sites, depends largely on the design of the technology, its proper fabrication and construction, and its proper operation. Consequently, quality assurance (QA) and quality control (QC) practices are needed to ensure that environmental technology successfully performs its intended role.

It is the policy (Ref. 1) of EPA that all environmental programs conducted by or on behalf of EPA shall establish and implement effective quality systems to support those programs. This policy

[1]Environmental data include any parameters or pieces of information collected or produced from measurements, analyses, or models of environmental processes and conditions and effects of pollutants on human health and the ecology, including results from laboratory analyses or from experimental systems representing such processes and conditions.

requires that all Agency organizational units document their quality system [2] in an approved Quality Management Plan (QMP). This plan provides the blueprint for how an individual Agency component will plan, implement, and assess its quality system for the environmental work to be performed as part of its mission.

QMPs submitted by organizations performing work for EPA as evidence of that organization's established quality system are reviewed and approved by authorized EPA personnel as part of the contracting or assistance agreement processes.

The QMP is the blueprint for how the organization will conduct its business. The QMP defines an organization's QA-related:

- policies and procedures,
- criteria for and areas of application, and,
- roles, responsibilities, and authorities.

The QMP is a management tool that should be appropriately tailored to the needs of its organization and that defines how its quality management objectives will be attained. The QMP must be sufficiently inclusive, explicit, and readable to enable managers and supervisors to understand the priority which management places on QA, the established QA policies and procedures, and their respective QA roles. The QMP must be constructed and written so that an assessment of its effectiveness following implementation will permit the determination of whether or not the quality system is being managed in a way that assures successful environmental programs. In practice, the QMP should be focused on the processes used to plan, implement, and assess the programs to which it is applied. The level of detail shall be based on a common sense, graded approach [3] that establishes QA and QC requirements commensurate with the importance of the work, the available resources, and the unique needs of the organization.

QMPs may be tailored to individual requirements and modified as the requirements change. This document describes the quality management practices which are normally considered to be critical to a quality system. Some elements are mandatory to ensure consistency across EPA-related quality systems. Other elements may be mission-specific and may not apply to every organization. Each organization should evaluate these key elements to see if they are applicable to their quality

[2] A quality system is a structured and documented management system describing the policies and procedures for ensuring that work processes, products, or services satisfy stated expectations or specifications. A more complete definition is given in the appendix.

[3] A graded approach to QA/QC bases the level of managerial controls on the intended use of the results and the degree of confidence needed in the quality of the results.

system. Where a particular element is not relevant, a brief explanation of why it is not relevant should be provided in the quality management document. On the other hand, if the QMP preparer determines that additional quality management elements are useful or necessary for an adequate quality system, these elements should be developed and discussed in the quality system documents.

CHAPTER II

QUALITY MANAGEMENT PLAN PREPARATION, SUBMISSION, REVIEW, AND APPROVAL

The following discussions pertain to the roles of senior managers and line managers in the preparation, submission, review, and approval of QMPs. The chapter also defines the role of the Quality Assurance Manager (QAM) in this process. EPA's specific internal preparation, review, and approval process for EPA QMPs is not relevant to this discussion and is not included here.

QMP Preparation Responsibility

An organization's senior manager is responsible for the preparation of a QMP to cover all environmental programs. The term *senior manager* refers to managers who are responsible and accountable for mission accomplishment and overall operations. The term *management or line management* refers to those individuals directly responsible and accountable for planning, implementing, and assessing environmental programs. Senior management is responsible for ensuring that the quality system documented in the QMP meets all statutory, contractual, and assistance agreement requirements for EPA work.

While senior management is responsible for the preparation of the QMP, the physical preparation may be assigned to the organization's staff so long as it is assured that all line managers participate in and support the effort. The preparation of the QMP may be directed by the QAM. It is essential that line management understand fully the content of the QMP and concur with its implementation.

QMP Submission and EPA Approval

The QMP must be approved and signed by the senior management of the organization preparing the QMP. This will certify that the organization has conducted an internal review of the QMP and that line management has concurred with its contents.

When review and approval of QMP by EPA is required either by statute, contractual requirement, or assistance agreement condition, the QMP must be submitted for review to the EPA organization responsible for the work to be performed. For example, the review of a State QMP that has been submitted as part of a request for an assistance agreement will be performed by the Region or Office making the decision on the assistance request. EPA will approve those QMPs that include acceptable QA policies, procedures, administrative criteria, and management systems for key QA elements including Data Quality Objectives, QA Project Plans, other QMPs, Standard Operating Procedures, assessments, and oversight of delegated programs.

QMP Revisions

Even though the QMP approval by the Agency is valid for up to five years, EPA policy requires that all agency quality systems be reviewed at least annually by their organizations to reconfirm the effectiveness of the approved quality management practices. This assessment must also include an evaluation of the effectiveness of the QMP. The process of developing and annually updating the QMP provides an opportunity for management and staff to clarify roles and responsibilities, address problem areas, and acknowledge successes so that they may be fostered and rewarded. Having an accurate QMP at all times is an essential element in every Quality System. Changes in QA policy and procedures should be documented in timely fashion by QMP revisions. In general, a copy of any QMP revision(s) made during the year should be submitted to EPA as a report when such changes occur. In some cases, however, it may be necessary to re-submit the entire QMP if significant changes have been made to the Quality System that significantly affects the performance of work for the Agency.

It is recommended that all appropriate personnel performing work for the organization, including active contractors and assistance agreement holders be notified of all changes to the Quality System and the QMP to keep them apprised of the current requirements.

CHAPTER III

QUALITY MANAGEMENT PLAN REQUIREMENTS

Quality management begins with the QMP. The QMP is the blueprint for an organization's quality management process in support of technical operations. The QMP should describe how the organization plans and implements the necessary quality management practices, including QA/QC, to help management to ensure that the results of technical work are of the type and quality needed for their intended use.

Accordingly, the QMP shall discuss:

- the mission and quality policy of the organization,
- the specific roles and responsibilities of management and staff with respect to QA/QC activities,
- the means by which effective communications are assured,
- the process(es) used to plan, implement, and assess the work performed,
- the process by which measures of effectiveness for QA/QC will be established and how frequently effectiveness will be measured, and
- the process for continuous improvement.

The QMP must reflect the organization's commitment to quality management principles and practices, tailored by senior management to meet the organization's needs. For the purposes of uniformity and to ensure a consistent and complete review of the QMP, it is preferable, but not necessary, that the QMP address the specifications in the same order as presented below. If an existing, approved QMP adequately addresses each of these topics, but in a different order, it should not be rewritten simply to conform to the outline provided here. The important element here is content, not format. A discussion is provided under each topic heading to clarify the type of information that is expected to be presented in a QMP.

If an organization believes that an element is not applicable to its quality system, then it must state why this is the case. In the discussions to follow, specific requirements within each of these program elements are given.

1 MANAGEMENT AND ORGANIZATION

Specifications:

Provide or address the following management and organizational items:

- a statement of the organization's policy on quality assurance, including:
  - the importance of QA/QC to the organization and why,
  - the general objectives/goals of the quality system, and
  - the policy for resource allocation for the quality system;
- an organization chart that identifies all of the components of the organization and, in particular, the organizational position of the QA Manager that documents the independence of the QA Manager from groups generating environmental data;
- a discussion of the responsibilities and authorities of the QA Manager and any other QA staff, including the line of reporting to senior management;
- A discussion of the technical activities or programs that are supported by the quality system and to which it applies; that is, the specific programs that require extensive quality management controls; where oversight of delegated, contracted, or other extramural programs is needed to assure data quality; and, where internal coordination of QA and QC among the group's organizational units needs to occur.
- a discussion of the QA/QC roles and responsibilities of line management, technical staff, and any other staff;
- identification of the types of environmental programs to which the quality system is to be applied;
- a discussion of how management will assure that applicable elements of the quality system are understood and implemented in all environmental programs; and
- an approval page for the signatures of the accountable managers, senior line

management (as appropriate), and the QA manager of the organization, and for the responsible EPA official. The EPA official may include the project officer (for contracts), the work assignment manager (for work assignments), the award official (for assistance agreements), and the EPA QA manager. This approval page may be part of a title page or a separate sheet following the title page.

Rationale:

The QMP represents an opportunity for the senior manager of an organization to inform subordinates of the priority accorded to the quality system and the reasons for that priority. The QMP documents important broad quality policies of the organization such as the requirement to incorporate QA in the up-front planning of activities entailing environmental data collection and the need for personal involvement of subordinate managers and supervisors in day-to-day QA/QC activities.

The QMP should identify the programmatic activities of the associated organizations covered by the quality system and describe its structure, policies and procedures, functional responsibilities, levels of accountability and authority, and necessary interfaces. By identifying and describing these activities (i.e., types of projects, tasks, etc.), the organization specifies the necessary foundation for defining and stipulating the items that are essential to planning an effective quality system.

2 QUALITY SYSTEM AND DESCRIPTION

Specifications:

The QMP shall contain or address the following items pertaining to the quality system and the technical mission to which it applies:

- A discussion of the principal components or "tools" comprising the quality system and their use. These components include, but are not limited to:

  - Quality Management Plans
  - Management Systems Reviews (Self and Independent)
  - Data Quality Objectives
  - QA Project Plans
  - Standard Operating Procedures
  - Technical Assessments (Self and Independent)
  - Data Quality Assessments

  The discussion should describe the how the "tools" are used and must include the roles and responsibilities of all management and staff involved in planning and

implementing the quality system.

Rationale:

The QMP should describe the quality system "tools" and processes used by the organization to plan, implement, and assess the effectiveness of QA/QC activities applied to its environmental programs. Such a process description should include how key QA/QC functions are to be performed, what "tools" or procedures are used, and who is responsible for doing the work.

The QMP should define general QA and QC activities to be used and document *how and when* they are to be applied to individual projects and tasks. The QMP is the formal means by which management documents how QA and QC will be applied to environmental programs; that is, the QMP provides the "blueprint" for how the Quality system will operate. Moreover, the QMP provides the basis for assessing the overall effectiveness of the quality system.

3 PERSONNEL QUALIFICATION AND TRAINING

Specifications:

Describe the processes for:

- identifying statutory, regulatory, or professional certifications that may be required to perform certain operations; and
- identifying, designing, performing, and documenting technical, quality, and project management training.

Rationale:

Personnel performing work on environmental programs must be qualified to perform assigned work, including and according to any project-specific requirements. This section should describe the organization's process for establishing training requirements, identifying training needs, assigning priorities to them, and satisfying them.

4 PROCUREMENT OF ITEMS AND SERVICES

Specifications:

This section of the QMP shall discuss the organization's process for ensuring that contracted and subcontracted activities produce results of acceptable quality, including, as appropriate:

- procurement source evaluation and selection,
- evaluation of objective evidence of quality furnished by the supplier,
- source inspections,
- supplier audits, and
- examination of deliverables.

Procurement documents or assistance agreements shall require suppliers (i.e., contractors, subcontractors, or financial assistance recipients) to have a quality system consistent with EPA requirements. *This requirement applies only to those suppliers who provide services or items that directly affect the quality of results or products from environmental programs.*

Rationale:

The procurement process must ensure that approved suppliers continue to provide acceptable items and services. The management system should describe: the planning of procurement needs and activities; the identification, documentation, review, and approval of technical specifications; the selection and documentation of evaluation criteria and necessary certifications; the qualification of contractors and subcontractors; the evaluation of contractor and subcontractor QMPs to ensure compliance with the guidelines presented in this requirements document; the identification of procedures for review and approval of negotiations, compromises or changes regarding technical issues; documentation of the procurement process; and the evaluation and verification of post-award quality versus original acceptance criteria.

Suppliers are responsible for the quality of items and services provided by their subcontractors and suppliers.

5 DOCUMENTATION AND RECORDS

Specifications:

Describe or provide a reference to the process:

- for identifying quality-related documents and records requiring control;
- for handling documents and records to assure their accessibility, protection from damage and deterioration, and means of retention, including discussion of the roles and responsibilities for management and staff;
- by which all technical guidance documents are prepared, reviewed, approved, issued, used, and revised; and

- that ensures compliance with all statutory, contractual, and assistance agreement requirements for records from environmental programs and that provides adequate preservation of key records necessary to support the mission of the organization.

The QMP must describe or provide a reference to the management process that controls preparation, review, approval, issuance, use, and revision of planning documents; i.e., QA Project Plans, Sampling and Analysis Plans. Such documents, including revisions, must be reviewed for conformance with the quality system requirements and approved by authorized personnel for general use. To facilitate the use of documents, consistency in formats is encouraged for similar types of documents, such as Standard Operating Procedures (SOPs).

The QMP must also describe or provide a reference to the management process for records to ensure that they accurately reflect completed work and/or fulfill statutory and contractual requirements. The maintenance of records includes defining requirements and responsibilities for record transmittal, distribution, retention, protection, preservation, traceability, disposition, and retrievability. To facilitate their accessibility and use, records must comply with required formats such as that required for analytical data by Good Automated Laboratory Practices (GALP) (Ref. 2). The QMP should also identify how the disposition of records, in accordance with regulatory requirements, schedules, or directives from senior management, is accomplished.

Rationale:

Organizations that perform environmental sampling, analysis, and project management activities must establish and maintain procedures for the timely preparation, review, approval, issuance, use, control, revision and maintenance of documents and records. For the purposes of these requirements, a document is any compilation of information which describes, defines, specifies, reports, certifies, requires, or provides data or results pertaining to environmental programs. A record is a completed document that provides objective evidence of an item or process.

6 COMPUTER HARDWARE AND SOFTWARE

Specifications:

This section of the QMP shall address the use of computer hardware and software in the organization's environmental operations that specifically support environmental programs and potentially affect the quality of their results. Specifically, the QMP must:

- describe the process for ensuring that computer hardware used in environmental programs meets the requirements of these programs;

- describe how changes to hardware shall be controlled to assess the impact of the

change on performance;

- describe briefly or reference the process for developing computer software, for validating, verifying, and documenting the software for its use, and for assuring that the software meets the requirements of the user;

- describe how purchased software is evaluated to meet user requirements and to comply with applicable contractual requirements and standards; and

- describe or reference the process for ensuring that data and information produced from or collected by computers meet applicable Information Resource Management (IRM) requirements and standards.

These descriptions shall include the roles and responsibilities assigned to management and staff.

Rationale:

There is increasing dependence on computer hardware and software to support environmental programs. Computer hardware must be appropriate for its intended application. Computer programs used in environmental data operations and for environmental technology design, construction, and operation should be developed using an approved software development methodology. Computer programs covered by this policy include but are not limited to design, design analysis, modeling of environmental processes and conditions, operations or process control, and data bases or document control registers (when used as the controlled source of quality information). The QMP should document how the organization manages its computer hardware and software operations that directly impact the quality of the results of environmental programs.

7 PLANNING

Specifications:

Describe the process for planning environmental programs, including who is responsible and how general project planning is documented. Environmental data operations shall be planned using a systematic planning process that encompasses the graded approach. The planning process must ensure that all organizations and/or parties who contribute to the quality of the environmental program or use the results are identified and that they participate in this process. The planning process must include direct communication between the customer and the supplier to ensure that there is a clear understanding by all participants of the needs and expectations of the customer and the product or results to be provided by the supplier.

The results of planning for environmental data operations shall be documented in a Quality

Assurance Project Plan (QAPP) and approved by authorized personnel for implementation.

Rationale:

Projects involving the generation, acquisition and use of environmental data may be planned using a systematic planning process such as the Data Quality Objectives process. When used, the DQO process will:

- identify the customer for whom the work is to be performed,
- identify the needs and expectations of the customer in terms of both technical and quality goals,
- translate the customer's needs into specifications to produce the desired result,
- consider any cost and schedule constraints within which project activities are required to be performed, and
- identify acceptance criteria for the result or measures of performance by which customer satisfaction will be determined.

The QMP should describe how all work is accomplished in the proper sequence and in accordance with approved planning documentation. All environmental programs do not require the same degree of quality control.

8 IMPLEMENTATION OF WORK PROCESSES

Specifications:

Describe the process of how and by whom work shall be implemented by the organization. Minimally, the QMP must describe:

- the procedures for ensuring that work is performed according to plan;
- the development and implementation of procedures for appropriate routine, standardized, special, or critical operations, including those that address, but are not limited to:
  - identification of operations needing procedures;
  - preparation of procedures, including form, content, and applicability; and
  - review and approval of procedures.

The QMP must stress that environmental data operations will be implemented in accordance with the approved QAPP. The QMP shall consider those activities, policies, and procedures that are common to all projects. It must also emphasize the importance of documenting activities including any exceptions to the QAPP.

The QMP shall describe how appropriate measures for controlling the release, change, and use of planned procedures are implemented. These measures shall provide for the necessary approvals, specific times and points for implementing changes, removal of obsolete documentation from work areas, and verification that the changes are made as prescribed.

Rationale:

Line managers are responsible for implementing the approved QAPP and the QMP. This includes organizing and planning activities to meet quality requirements consistently; coordinating work performance for specific projects; and training and qualifying personnel to achieve and maintain proficiency. The mechanism for implementing these responsibilities should be described in the QMP.

Standard operating procedures (SOPs) are encouraged for appropriate routine, standardized, or special/critical operations. The QMP should contain policies and procedures for identifying and addressing SOPs. The QMP should also describe the review process by which SOP adequacy will be determined by technically qualified personnel before an SOP is used.

9 ASSESSMENT AND RESPONSE

Specifications:

Assessments are evaluations intended to provide an increased understanding of the program or system being examined, and to provide a basis for improving such programs or systems. This section of the QMP must describe how and by whom assessments of environmental programs are planned, conducted, and evaluated. This section shall also describe the process by which management determines the assessment activities appropriate for a particular project, which assessment tools[4] may be used and the expected frequency of use.. The assessment tools for environmental programs include:

- management systems reviews,
- surveillances,
- audits,
- performance evaluations,

[4]Please see the Appendix for complete definitions of these assessment tools.

- audits of data quality,
- peer reviews and technical reviews,
- readiness reviews, and
- data quality assessments.

This section shall contain or address the following items pertaining to management assessment of the effectiveness of the organization's quality system:

- how the process for the planning, scheduling, and implementation of assessments works, as well as how the organization will respond to needed changes;

- responsibilities, levels of participation, and authorities for all management and staff involved in the assessment process; and

- how, when, and by whom actions will be taken in response to the findings of the assessment, and how the effectiveness of the response will be determined.

Personnel conducting assessments shall be qualified, based on project-specific requirements, to perform the assigned assessment. The QMP must describe how the level of competence, experience, and training necessary to ensure the capability of personnel conducting assessments are determined. The QMP shall document that persons conducting assessments have sufficient authority, access to programs and managers, access to documents and records, and organizational freedom to:

- identify quality problems;
- identify and cite noteworthy practices that may be shared with others to improve the quality of their operations and products;
- propose recommendations for resolving quality problems; and
- independently confirm implementation and effectiveness of solutions.

The QMP must clearly define the responsibilities and authorities of personnel conducting assessments, particularly in regard to authority to suspend or stop work in progress upon detection and identification of an immediate adverse condition affecting the quality of results.

The QMP must describe how management will respond to the results (or findings) and recommendations from assessments in a timely manner. When conditions needing corrective action are identified, the appropriate response must be made promptly. The QMP should indicate how follow-up action will be taken and documented to confirm the implementation and effectiveness of the response action.

Data obtained from sources that did not use a QAPP (or equivalent planning document) for data collection must be qualified. The process for qualifying such data shall be documented in the QMP. This process shall include the correct application of statistical methods during the assessment

process. The decision to qualify the data for their intended use shall be based on reconciliation with the performance measures for the project defined by the data quality requirements. Any limitations on data use shall be identified quantitatively to the extent practicable and fully documented.

Assessments should include an evaluation to determine whether technical requirements, not just procedural compliance, are being met effectively. Assessments should be performed according to approved written procedures from management, based on careful planning, the scope of the assessment, and the information needed. The QMP should describe how assessment results shall be documented, reported to, and reviewed by management.

Rationale:

The type of assessment to be used in a particular application is determined by management. Four general types of assessments are:

- **management self-assessment**: the qualitative assessment of a particular program operation and/or organization(s) *by those immediately responsible for overseeing and/or performing the work* to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of results needed are obtained.

- **management independent assessment**: the qualitative assessment of a particular program operation and/or organization(s) *by someone other than the group performing the work* to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of results needed are obtained.

- **technical self-assessment**: the evaluation process used *by those immediately responsible for overseeing and/or performing the work* to measure the performance or effectiveness of a technical system and its elements with respect to documented specifications and objectives. Such assessments may include qualitative and quantitative evaluations.

- **technical independent assessment**: the evaluation process used *by someone other than the group performing the work* to measure the performance or effectiveness of a technical system and its elements with respect to documented specifications and objectives. Such assessments may involve qualitative and quantitative evaluations, and may include peer reviews and audits.

Management is responsible for choosing the assessors, defining acceptance criteria, approving audit check lists, and identifying goals prior to initiation of an assessment. Assessors are technically knowledgeable people with no real or perceived conflict of interest. If the assessors are chosen from

within the organization, they must have no direct involvement or responsibility for the work being assessed.

Senior management is required to assess (at least annually) the adequacy of the quality system. The organization's approved QMP provides the basis for these assessments. Such assessments provide a means for determining and taking necessary response actions regarding:

- effectiveness of the system of management controls that are established to achieve and assure quality, and
- adequacy of resources and personnel provided to achieve quality objectives in all activities to which the Quality System applies.

These planned and periodic management assessments, using the Management Systems Reviews (MSR) process (Ref. 3), should be implemented as prescribed in the QMP. Management assessments address the effectiveness of management controls in achieving and assuring quality, the adequacy of resources and personnel, the effectiveness of training and assessments, and applicability of data quality requirements. Management assessments determine both noteworthy accomplishments and significant QA problems, and identify opportunities for improvement.

10 QUALITY IMPROVEMENT

Specifications:

Describe the organization's management system for detecting and preventing quality problems and for ensuring continuous quality improvement, including:

- the management process and identify who (organizationally) is responsible for identifying, planning, implementing, and evaluating the effectiveness of quality improvement activities;
- a corrective action program to ensure that conditions adverse to quality are identified promptly and corrected as soon as practical.

Corrective actions shall include the identification of root causes of problems, the determination of whether the problem is unique or has more generic implications, and a recommendation of procedures to prevent recurrence.

Rationale:

The process of continuous quality improvement leads to the development of a better and more

responsive quality system. Quality problems are often inherent in existing management and technical systems, and workers may have little or no control over eliminating these problems or improving performance. In environmental programs, quality improvement generally results from activities that:

- prevent or minimize problems during the planning and implementation of environmental programs that may affect the quality of the results;
- detect and correct the problems; and
- review existing performance and identify opportunities for quality improvement.

The QMP should describe how staff at all levels are encouraged to identify and establish communications among customers and suppliers, identify process improvement opportunities, identify problems, and offer solutions to those problems. Motivation of staff begins with their understanding of the tasks they are expected to perform and how those tasks support the overall mission of the organization.

SUMMARY

The QMP is the management "blueprint" for applying QA/QC to environmental programs. The QMP defines the unique quality system for planning, implementing, and assessing the effectiveness of activities supporting environmental data operations and other environmental programs. The QMP provides the principal basis for management reviews of an organization's quality system.

The requirements given in this document are consistent with national and international standards for quality management systems. Because of the importance of the QMP, it must be kept current and must be readily available to all managers and staff responsible for planning and implementing environmental programs.

REFERENCES

(1) EPA Order 5360.1, *Policy and Program Requirements to Implement the Mandatory Quality Assurance Program*, U.S. Environmental Protection Agency, Washington, DC (April 1984).

(2) *Good Automated Laboratory Practices*, U.S. Environmental Protection Agency, Washington, DC (Draft, December 1990).

(3) *Guidance for the Management Systems Review Process* (EPA QA/G-3), U.S. Environmental Protection Agency, Washington, DC (IN PROCESS).

APPENDIX A

TERMS AND DEFINITIONS

activity - an all-inclusive term describing a specific set of operations or related tasks to be performed, either serially or in parallel (e.g., research and development, field sampling, analytical operations, equipment fabrication), that in total result in a product or service.

assessment - the evaluation process used to measure the performance or effectiveness of a system and its elements. As used here, assessment is an all-inclusive term used to denote any of the following: audit, performance evaluation, management systems review, peer review, inspection, or surveillance.

audit (quality) - a systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

auditee - the organization being audited.

auditor - a person qualified to perform audits.

authenticate - the act of establishing an item as genuine, valid, or authoritative.

bias - the systematic or persistent distortion of a measurement process which causes errors in one direction (i.e., the expected sample measurement is different from the sample's true value).

calibration - comparison of a measurement standard, instrument, or item with a standard or instrument of higher accuracy to detect and quantify inaccuracies and to report or eliminate those inaccuracies by adjustments.

chain of custody - an unbroken trail of accountability that ensures the physical security of samples, data, and records.

characteristic - any property or attribute of a datum, item, process, or service that is distinct, describable, and/or measurable.

comparability - a measure of the confidence with which one data set can be compared to another.

completeness - a measure of the amount of valid data obtained from a measurement system compared to the amount that was expected to be obtained under correct, normal conditions.

computer program - a sequence of instructions suitable for processing by a computer. Processing may include the use of an assembler, a compiler, an interpreter, or a translator to prepare the program for execution. A computer program may be stored on magnetic media, and be referred to as "software," or may be stored permanently on computer chips, and be referred to as "firmware." Computer programs covered by this Standard are those used for design analysis, data acquisition, data reduction, data storage (data bases), operation or control, and data base or document control registers when used as the controlled source of quality information.

confidentiality procedure - a procedure used to protect confidential business information (including proprietary data and personnel records) from unauthorized access.

configuration - the functional, physical, and procedural characteristics of an item, experiment, or document.

conformance - an affirmative indication or judgement that a product or service has met the requirements of the relevant specifications, contract, or regulation; also the state of meeting the requirements.

consensus standard - a standard established by a group representing a cross section of a particular industry or trade, or a part thereof.

contractor - any organization or individual that contracts to furnish services or items or perform work.

corrective action - measures taken to rectify conditions adverse to quality and, where possible, to preclude their recurrence.

client - any individual or organization for whom items or services are furnished or work performed in response to defined requirements and expectations. See also Participant and User.

data of known quality - data that have the qualitative and quantitative components associated with their derivation documented appropriately for their intended use, and when such documentation is verifiable and defensible.

data quality assessment (DQA) - a statistical and scientific evaluation of the data set to determine the validity and performance of the data collection design and statistical test, and to determine the adequacy of the data set for its intended use.

data quality objectives (DQOs) - Qualitative and quantitative statements derived from the DQO Process that clarify study technical and quality objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions.

Data Quality Objectives Process - a systematic strategic planning tool based on the scientific method that identifies and defines the type, quality, and quantity of data needed to satisfy a specified use. The key elements of the process include:

- concisely defining the problem,
- identifying the decision to be made,
- identifying the key inputs to that decision,
- defining the boundaries of the study,
- developing the decision rule,
- specifying tolerable limits on potential decision errors, and
- selecting the most resource efficient data collection design.

Data quality objectives are the qualitative and quantitative outputs from the DQO Process. The DQO Process was developed originally by the U.S. Environmental Protection Agency, but has been adapted for use by other organizations to meet their specific planning requirements. (See also Graded Approach)

data usability - the process of ensuring or determining whether the quality of the data produced meets the intended use of the data.

deficiency - an unauthorized deviation from acceptable procedures or practices, or a defect in an item.

demonstrated capability - the capability to meet procurement technical and quality specifications through evidence presented by the supplier to substantiate its claims and in a manner defined by the customer.

design - specifications, drawings, design criteria, and performance requirements. Also the result of deliberate planning, analysis, mathematical manipulations, and design processes.

design change - any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

design review - a documented evaluation by a team, including personnel such as the responsible designers, the client for the work or product being designed, and a QA representative, but other than the original designers, to determine if a proposed design will meet the established design criteria and perform as expected when implemented.

document - any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results.

entity - that which can be individually described and considered, such as a process, product, item,

organization, or combination thereof.

environmental conditions - the description of a physical medium (e.g., air, water, soil, sediment) or biological system expressed in terms of its physical, chemical, radiological, or biological characteristics.

environmental data - any parameters or pieces of information collected or produced from measurements, analyses, or models of environmental processes, conditions, and effects of pollutants on human health and the ecology, including results from laboratory analyses or from experimental systems representing such processes and conditions.

environmental data operations - work performed to obtain, use, or report information pertaining to environmental processes and conditions.

environmental monitoring - the process of measuring or collecting environmental data.

environmental processes - manufactured or natural processes that produce discharges to or that impact the ambient environment.

environmental programs - an all-inclusive term pertaining to any work or activities involving the environment, including but not limited to: characterization of environmental processes and conditions; environmental monitoring; environmental research and development; the design, construction, and operation of environmental technologies; and laboratory operations on environmental samples.

environmental technology - an all-inclusive term used to describe pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies and their components that may be utilized to remove pollutants or contaminants from or prevent them from entering the environment. Examples include wet scrubbers (air), soil washing (soil), granulated activated carbon unit (water), and filtration (air, water). Usually, this term will apply to hardware-based systems; however, it will also apply to methods or techniques used for pollution prevention, pollutant reduction, or containment of contamination to prevent further movement of the contaminants, such as capping, solidification or vitrification, and biological treatment.

evidentiary records - records identified as part of litigation and subject to restricted access, custody, use, and disposal.

expedited change - an abbreviated method of revising a document at the work location where the document is used when the normal change process would cause unnecessary or intolerable delay in the work.

financial assistance - the process by which funds are provided by one organization (usually government) to another organization for the purpose of performing work or furnishing services or

items. Financial assistance mechanisms include grants, cooperative agreements, and government interagency agreements.

finding - an assessment conclusion that identifies a condition having a significant effect on an item or activity. An assessment finding may be positive or negative, and is normally accompanied by specific examples of the observed condition.

grade - the category or rank given to entities having the same functional use but different requirements for quality.

graded approach - the process of basing the level of application of managerial controls applied to an item or work according to the intended use of the results and the degree of confidence needed in the quality of the results. (See Data Quality Objectives Process)

guideline - a suggested practice that is non-mandatory in programs intended to comply with a standard.

hazardous waste - any waste material that satisfies the definition of "hazardous waste" as given in 40 CFR Part 261, "Identification and Listing of Hazardous Waste."

independent assessment - an assessment performed by a qualified individual, group, or organization that is not a part of the organization directly performing and accountable for the work being assessed.

inspection - examination or measurement of an item or activity to verify conformance to specific requirements.

item - an all-inclusive term used in place of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, product, structure, subassembly, subsystem, system, unit, documented concepts, or data.

management - those individuals directly responsible and accountable for planning, implementing, and assessing work.

management system - a structured non-technical system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for conducting work and producing items and services.

Management Systems Review (MSR) - the qualitative assessment of a data collection operation and/or organization(s) to establish whether the prevailing quality management structure, policies, practices, and procedures are adequate for ensuring that the type and quality of data needed are obtained.

may - denotes permission but not a requirement.

measurement and testing equipment (M&TE) - tools, gauges, instruments, sampling devices or systems used to calibrate, measure, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

method - a body of procedures and techniques for performing an activity (e.g., sampling, chemical analysis, quantification) systematically presented in the order in which they are to be executed.

mixed waste - hazardous waste material as defined by 40 CFR 261 (RCRA) and mixed with radioactive waste subject to the requirements of the Atomic Energy Act.

must - denotes a requirement that has to be met.

nonconformance - a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate; nonfulfillment of a specified requirement.

objective evidence - any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.

observation - an assessment conclusion that identifies a condition (either positive or negative) which does not represent a significant impact on an item or activity. An observation may identify a condition which does not yet cause a degradation of quality.

organization - a company, corporation, firm, enterprise, or institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration.

organization structure - the responsibilities, authorities, and relationships, arranged in a pattern, through which an organization performs its functions.

participant - when used in the context of environmental programs, an organization, group, or individual that takes part in the planning and design process and provides special knowledge or skills to enable the planning and design process to meet its objective.

peer review - a documented critical review of work generally beyond the state of the art or characterized by the existence of potential uncertainty. The peer review is conducted by qualified individuals (or organization) who are independent of those who performed the work, but are collectively equivalent in technical expertise (i.e., peers) to those who performed the original work. The peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate

interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them. Peer reviews provide an evaluation of a subject where quantitative methods of analysis or measures of success are unavailable or undefined, such as in research and development.

performance evaluation (PE) - a type of audit in which the quantitative data generated in a measurement system are obtained independently and compared with routinely obtained data to evaluate the proficiency of an analyst or laboratory.

pollution prevention (P2) - an organized, comprehensive effort to systematically reduce or eliminate pollutants or contaminants prior to their generation or their release or discharge to the environment.

precision - a measure of mutual agreement among individual measurements of the same property, usually under prescribed similar conditions, expressed generally in terms of the standard deviation.

procedure - a specified way to perform an activity.

process - a set of interrelated resources and activities which transforms inputs into outputs. Examples of processes include analysis, design, data collection, operation, fabrication, and calculation.

project - an organized set of activities within a program.

qualified data - any data that have been modified or adjusted as part of statistical or mathematical evaluation, data validation, or data verification operations.

qualified services - an indication that suppliers providing services have been evaluated and determined to meet the technical and quality requirements of the client as provided by approved procurement documents and demonstrated by the supplier to the client's satisfaction.

quality - the totality of features and characteristics of a product or service that bear on its ability to meet the stated or implied needs and expectations of the user.

quality assurance (QA) - an integrated system of management activities involving planning, implementation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client.

quality assurance program description/plan - see quality management plan

quality assurance project plan (QAPP) - a formal document describing in comprehensive detail the necessary QA, QC, and other technical activities that must be implemented to ensure that the results of the work performed will satisfy the stated performance criteria.

quality control (QC) - the overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality.

quality improvement - a management program for improving the quality of operations. Such management programs generally entail a formal mechanism for encouraging worker recommendations with timely management evaluation and feedback or implementation.

quality indicators - measurable attributes of the attainment of the necessary quality for a particular environmental decision. Indicators of quality include precision, bias, completeness, representativeness, reproducibility, comparability, and statistical confidence.

quality management - that aspect of the overall management system of the organization that determines and implements the quality policy. Quality management includes strategic planning, allocation of resources, and other systematic activities (e.g., planning, implementation, and assessment) pertaining to the quality system.

quality management plan (QMP) - a formal document that describes the quality system in terms of the organizational structure, functional responsibilities of management and staff, lines of authority, and required interfaces for those planning, implementing, and assessing all activities conducted.

quality system - a structured and documented management system describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization for ensuring quality in its work processes, products (items), and services. The quality system provides the framework for planning, implementing, and assessing work performed by the organization and for carrying out required QA and QC.

radioactive waste - waste material containing radionuclides, or contaminated by radionuclides, subject to the requirements of the Atomic Energy Act.

readiness review - a systematic, documented review of the readiness for the start-up or continued use of a facility, process, or activity. Readiness reviews are typically conducted before proceeding beyond project milestones and prior to initiation of a major phase of work.

record (quality) - a document that furnishes objective evidence of the quality of items or activities and that has been verified and authenticated as technically complete and correct. Records may include photographs, drawings, magnetic tape, and other data recording media.

remediation - the process of reducing the concentration of a contaminant (or contaminants) in air, water, or soil media to a level that poses an acceptable risk to human health.

representativeness - a measure of the degree to which data accurately and precisely represent a characteristic of a population, parameter variations at a sampling point, a process condition, or an environmental condition.

reproducibility - the precision, usually expressed as variance, that measures the variability among the results of measurements of the same sample at different laboratories.

research (applied) - a process, the objective of which is to gain knowledge or understanding necessary for determining the means by which a recognized and specific need may be met.

research (basic) - a process, the objective of which is to gain fuller knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific applications toward processes or products in mind.

research development/demonstration - Systematic use of the knowledge and understanding gained from research and directed toward the production of useful materials, devices, systems, or methods, including prototypes and processes.

scientific method - the principles and processes regarded as necessary for scientific investigation, including rules for concept or hypothesis formulation, conduct of experiments, and validation of hypotheses by analysis of observations.

self-assessment - Assessments of work conducted by individuals, groups, or organizations directly responsible for overseeing and/or performing the work.

service - the result generated by activities at the interface between the supplier and the customer, and by supplier internal activities to meet customer needs. Such activities in environmental programs include design, inspection, laboratory and /or field analysis, repair, and installation.

shall - denotes a requirement that is mandatory whenever the criterion for conformance with the specification requires that there be no deviation. This does not prohibit the use of alternative approaches or methods for implementing the specification so long as the requirement is fulfilled.

should - denotes a guideline or recommendation whenever noncompliance with the specification is permissible.

significant condition - any state, status, incident, or situation of an environmental process or condition, or environmental technology in which the work being performed will be adversely affected sufficiently to require corrective action to satisfy quality objectives or specifications and safety requirements.

specification - a document stating requirements and which refers to or includes drawings or other

relevant documents. Specifications should indicate the means and the criteria for determining conformance.

software life cycle - the period of time that starts when a software product is conceived and ends when the software product is no longer available for routine use. The software life cycle typically includes a requirements phase, a design phase, an implementation phase, a test phase, an installation and check-out phase, an operation and maintenance phase, and sometimes a retirement phase.

source reduction - any practice that reduces the quantity of hazardous substances, contaminants, or pollutants.

standard operating procedure (SOP) - a written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks.

supplier - any individual or organization furnishing items or services or performing work according to a procurement document or financial assistance agreement. This is an all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, or consultant.

surveillance (quality) - continual or frequent monitoring and verification of the status of an entity and the analysis of records to ensure that specified requirements are being fulfilled.

technical review - a documented critical review of work that has been performed within the state of the art. The review is accomplished by one or more qualified reviewers who are independent of those who performed the work, but are collectively equivalent in technical expertise to those who performed the original work. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

technical systems audit (TSA) - a thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, recordkeeping, data validation, data management, and reporting aspects of a system.

Total Quality Management (TQM) - the process of applying quality management to all activities of the organization, including technical and administrative operations. See Quality Management and Quality System.

traceability - the ability to trace the history, application, or location of an entity by means of recorded identifications. In a calibration sense, traceability relates measuring equipment to national or international standards, primary standards, basic physical constants or properties, or reference materials. In a data collection sense, it relates calculations and data generated throughout the project back to the requirements for quality for the project.

user - when used in the context of environmental programs, an organization, group, or individual that utilizes the results or products from environmental programs. A user may also be the client for whom the results or products were collected or created.

validation - confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled. In design and development, validation concerns the process of examining a product or result to determine conformance to user needs.

verification - confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. In design and development, validation concerns the process of examining a result of a given activity to determine conformance to the stated requirements for that activity.

work - the process of performing a defined task or activity (e.g., research and development, field sampling, analytical operations, equipment fabrication).